REMARKS

The Applicants respectfully request reconsideration of this application in view of the above amendments and the following remarks.

35 U.S.C. §103(a) Rejection – Vigil, Kaplan, Hofling, or Faxon, and Hiki

The Examiner has rejected claims 1 and 3-9 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,102,904 issued to Vigil et al. (hereinafter "Vigil") or U.S. Patent No. 5,941,868 issued to Kaplan et al. (hereinafter "Kaplan") or U.S. Patent No. 5,354,279 issued to Hofling (hereinafter "Hofling") or U.S. Patent No. 5,464,395 issued to Faxon et al. (hereinafter "Faxon") in view of U.S. Patent No. 5,499,630 issued to Hiki et al. (hereinafter "Hiki"). The Applicants respectfully submit that the present claims are allowable over Vigil, Kaplan, Hofling, or Faxon and Hiki.

Claim 1 recites:

> "*A method comprising:*
> *positioning a delivery device at a location in a blood vessel;*
> ***imaging a thickness of a portion of a wall of the blood vessel at the location with an imaging assembly disposed in a lumen of the delivery device;***
> *identifying a treatment site based on the imaging;*
> *advancing the delivery device a distance into a wall of the blood vessel to the treatment site beyond an external elastic lamina of the blood vessel; and*
> *after advancing the delivery device, introducing a treatment agent through the delivery device*".

Vigil, Kaplan, Hofling, or Faxon and Hiki do not disclose these limitations or render them obvious. In particular, Vigil, Kaplan, Hofling, or Faxon and Hiki do not disclose or render obvious imaging a thickness of a portion of **a wall of the blood vessel** at the location with an imaging assembly **disposed in a lumen of the delivery device**, in combination with the other claim limitations.

The Examiner appears to have relied upon Hiki as disclosing the claimed imaging operation. See e.g., the bottom half of page 4 of the present Office Action.

Hiki discusses a catheter type ultrasound probe. See e.g., the Title. Hiki discusses an ultrasound probe having an ultrasound transducer mounted on a girder portion of a rigid fore end

section. What is described is an endoscopic ultrasound probe including rigid fore end section 6. See e.g., column 4, lines 22-37. Rigid fore end section 6 is provided with endoscopic observation means 11 on distal end phase 6a including illumination window 10 and observation window 11. Disposed in illumination window 10 is a light emitting end of a light guard. A lens is fitted in observation window 11 to form an optical image of a predetermined plane where a solid-state image sensor is located to take out the images for endoscopic observation. See e.g., column 4, lines 38-50. Mounted on rigid fore end section 6 is ultrasound transducer 20. See e.g., column 4, lines 55-60. An ultrasound image is displayed so that puncture needle 30 may be launched to penetrate an intracavitary wall into a target portion which needs a therapeutic treatment or examination. See e.g., column 6, lines 20-24. The example described relates to a stomach and inserting the catheter through the throat and esophagus. See e.g., column 5, lines 49-56.

However, Hiki does not disclose imaging a thickness of **a portion of a wall of the blood vessel** at the location with an imaging assembly **disposed in a lumen of the delivery device**, in combination with the other claim limitations. As noted above, the ultrasound probe of Hiki is directed at endoscopic examination /treatment and has its imaging device described as an ultrasound transducer on a rigid fore end section of the probe. Thus Hiki does not disclose an imaging assembly **disposed in a lumen of the delivery device**. As an endoscope device, Hiki describes its probe in relation to introduction in body cavities through, for example, the esophagus. Hiki does not describe routing a device through a blood vessel. In one sense, Hiki is on a scale potentially significantly larger than the scale to which the pending claim 1 is directed. Thus, one would not look to Hiki for teachings, suggestions, or motivations for imaging a thickness of a portion of a wall of a blood vessel. Further, Hiki describes an imaging device on a rigid fore end section. A rigid fore end section may be suitable for endoscopic operations but snaking a rigid device through one or many blood vessels presumably would be significantly more challenging.

For at least one or more of these reasons, independent claim 1, and its dependent claims are believed to be allowable over Vigil, Kaplan, Hofling, or Faxon and Hiki.

35 U.S.C. §103(a) Rejection – Kaplan, and Roorda or Slepian

The Examiner has rejected claims 10-27 under 35 U.S.C. §103(a) as being unpatentable over Kaplan in view of U.S. Patent No. 5,540,912 issued to Roorda et al. (hereinafter "Roorda") or U.S. Patent No. 5,575,815 issued to Slepian et al. (hereinafter "Slepian"). The Applicants respectfully submit that the present claims are allowable over Kaplan and Roorda or Slepian.

Claims 10-14 depend from claim 1 and therefore contain all the limitations of claim 1. Kaplan and Roorda or Slepian do not disclose or render obvious the limitations of claim 1. In particular, Kaplan and Roorda or Slepian do not disclose or render obvious imaging a thickness of a portion of **a wall of the blood vessel** at the location with an imaging assembly **disposed in a lumen of the delivery device**, in combination with the other claim limitations. The Examiner appears to have even admitted that Kaplan does not teach imaging a portion of a wall of a blood vessel. See e.g., the bottom of page 3 of the present Office Action. Roorda or Slepian also do not disclose imaging a thickness of a portion of **a wall of the blood vessel**. Accordingly, for at least one of these reasons, claim 1 and its dependent claims 10-14 are believed to be allowable over Kaplan and Roorda or Slepian.

Claims 15-22 have been cancelled without prejudice, therefore the rejection of these claims is believed to be moot.

Claim 23 recites:

> "*A composition comprising:*
> *at least one treatment agent disposed in a carrier, wherein the carrier comprises* ***particles having an average diameter of up to 10 microns****; and*
> ***an opsonin-inhibitor coupled to the carrier***".

Kaplan and Roorda or Slepian do not disclose these limitations or render them obvious. In particular, Kaplan and Roorda or Slepian do not disclose or render obvious: (1) wherein the carrier comprises **particles having an average diameter of up to 10 microns**; and (2) **an opsonin-inhibitor** coupled to the carrier, in combination with the other claim limitations.

In making the rejection, the Examiner has stated "*[i]t would have been obvious to one of ordinary skill in the art that an agent capable of promoting angiogenesis is also capable of being*

an opsonin-inhibitor and inducing an inflammation response". See e.g., the top of page 5 of the present Office Action.

Applicants respectfully disagree. It is not obvious that an agent capable of promoting angiogenesis is also capable of being an opsonin-inhibitor. Moreover, Kaplan and Roorda or Slepian do not disclose this. While the scope of the invention is only limited to the claims, examples of opsonin-inhibitors mentioned in the application include polyethylene glycol and glycocalyx-like molecules. See e.g., paragraphs [0058]-[0062] of the present patent application. Applicants respectfully submit that these or other opsonin-inhibitors are not disclosed in Kaplan and Roorda or Slepian.

For at least one or more of these reasons, claim 23, and its dependent claims are believed to be allowable over Kaplan and Roorda or Slepian.

35 U.S.C. §103(a) Rejection – Hofling and Hiki

The Examiner has rejected claims 28-31 under 35 U.S.C. §103(a) as being unpatentable over Hofling in view of Hiki. The Applicants respectfully submit that the present claims are allowable over Hofling and Hiki.

Claim 28 recites:

> "*An apparatus comprising:*
> *a catheter body capable of traversing a mammalian blood vessel;*
> *a dilatable balloon assembly coupled to the catheter body comprising a balloon having a proximal wall;*
> *at least one needle body disposed within the catheter body and comprising a lumen having dimensions suitable for a needle to be advanced therethrough,* ***the at least one needle body comprising an end coupled to the proximal wall of the balloon****;*
> *an imaging body disposed within the catheter body and comprising* ***a lumen having dimensions suitable for a portion of an imaging device to be advanced therethrough and adapted to be shared simultaneously or sequentially with a guidewire****; and*
> *a portion of an imaging device disposed within the imaging body and* ***capable of moving within the lumen of the imaging body*** *and adapted to generate imaging signals of the blood vessel*".

Hofling and Hiki do not disclose these limitations or render them obvious. In particular, Hofling and Hiki do not disclose or render obvious: (1) the at least one needle body comprising

an end coupled to the proximal wall of the balloon; or (2) an imaging body comprising a lumen having dimensions suitable for a portion of an imaging device to be advanced therethrough and adapted to be shared simultaneously or sequentially with a guidewire and in which the portion of the imaging device is capable of moving within the lumen of the imaging body, in combination with the other claim limitations.

Hofling discusses a plural needle injection catheter. See e.g., the Title. FIG. 8 shows a catheter having a balloon 211. However, Hofling does not disclose that balloon 211 has a proximal wall having at least one needle body comprising an end coupled thereto.

Hiki was discussed above in conjunction with claim 1. As discussed above, Hiki does not disclose an imaging body comprising a lumen having dimensions suitable for a portion of an imaging device to be advanced therethrough and adapted to be shared simultaneously or sequentially with a guidewire and in which the portion of the imaging device is capable of moving within the lumen of the imaging body.

For at least one or more of these reasons, independent claim 28, and its dependent claims are believed to be allowable over Hofling and Hiki.

New Claims 38-43 Also Believed Allowable

Claim 38 recites:

> "*A method comprising:*
> *positioning a delivery device at a location in a blood vessel;*
> *advancing the delivery device a distance into a wall of the blood vessel to a treatment site beyond an external elastic lamina of the blood vessel; and*
> *after advancing the delivery device,* ***introducing a treatment agent through the delivery device,***
> ***wherein the treatment agent comprises an inflammation-inducing agent***".

As understood by Applicants, the cited art presently relied upon by the Examiner does not disclose or render obvious **introducing a treatment agent through the delivery device (into a wall of the blood vessel), wherein the treatment agent comprises an inflammation-inducing agent**, in combination with the other claim limitations. In particular, none of these

references appears to recognize the advantages of introducing inflammation-inducing agent into a wall of the blood vessel.

For at least one or more of these reasons, independent claim 38, and its dependent claims are believed to be allowable.

Conclusion

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the cited art of record and are in condition for allowance. Applicants respectfully request that the rejections be withdrawn and the claims be allowed at the earliest possible date.

Request For An Extension Of Time

The Applicants respectfully petition for an extension of time to respond to the outstanding Office Action pursuant to 37 C.F.R. § 1.136(a) should one be necessary. Please charge our Deposit Account No. 02-2666 to cover the necessary fee under 37 C.F.R. § 1.17 for such an extension.

Charge Our Deposit Account

Please charge any shortage to our Deposit Account No. 02-2666.

Respectfully submitted,
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Dated: 2/20/09

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CERTIFICATE OF TRANSMISSION
I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

Nedy Calderon 2/20/09
Nedy Calderon Date